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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/981,665	11/05/1997	STAN CIPKOWSKI	3000	8326

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1641	

MAIL DATE	DELIVERY MODE
08/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/981,665	CIPKOWSKI, STAN	
	Examiner	Art Unit	
	James L. Grun	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The amendment filed 21 May 2007 is acknowledged and has been entered. Claims 16-19 remain in the case.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claims 16-19 are rejected under 35 U.S.C. 112, first paragraph, for reasons similar to those of record as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With regard to the claims as now amended, the specification, as originally filed, does not provide support for a sample receiving portion on the exposed (i.e., front) **surface of the test strip** so that liquid sample flows through the sample receiving opening and directly contacts the exposed (i.e., front) surface of the sample receiving portion directly beneath the opening. As set forth, applicant provides no guidance in the specification for certain particulars of the test strip structure. Again, there is no disclosure in the instant specification regarding whether the instant test strip does or does not include an absorbent pad at the sample receiving portion. Applicant, in this regard, merely discloses that specimen is able to contact the "absorbent or sample

portions" of the test strips through the sample openings (see e.g. page 12). Moreover, there is no specific teaching in the instant specification regarding whether the instant test strips do or do not include the conventional backing or sandwiching with plastic taught in May et al. (WO 88/08534). Such sandwiching would affect the size and shape of the "sample receiving portion" and, as taught in some conventional test strip references (see e.g. Lee-Own et al., US 5,500,375), the "sample portion" may only be the cut end. Thus, there is nothing to support that the "sample receiving portions" of the test strips are directly exposed directly beneath the opening as is now claimed. Inclusive disclosure of several formerly commercially available test strips does not provide explicit or implicit indication to one of skill in the art that the invention was contemplated as limited to particular undisclosed structural interrelationships selected from a range of possible designs. Although one of skill in the art might realize from reading the disclosure that absorbent or sample receiving portions on the exposed (i.e., front) surface of the test strips are useable in the invention, such possibility of use does not provide explicit or implicit indication to one of skill in the art that such were originally contemplated as part of applicant's invention and such possibility of use does not satisfy the written description requirements of 35 U.S.C. § 112, first paragraph. Note that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement. Applicant is requested to direct the Examiner's attention to specific passages where support for these newly recited limitations can be found in the specification as filed or is required to delete the new matter.

Applicant's arguments filed 21 May 2007 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, applicant's

amendments have not obviated rejections under this statute for the reasons of record and as set forth above. As set forth, description of such structural/functional elements of the test strips as are now claimed are entirely lacking in the specification as filed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> (c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 16 and 19 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over May et al. (WO 88/08534) in view of Sun et al. (US 5,238,652) for reasons of record.

Claims 16-19 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over May et al. (WO 88/08534) in view of Sun et al. (US 5,238,652), and further in view of Boger et al. (US 4,518,565) for reasons of record.

Applicant's arguments filed 21 May 2007 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons and arguments of record incorporated herein.

Applicant's arguments regarding undisclosed features of the test strips were not found persuasive for the reasons set forth above under 35 USC 112 and incorporated herein.

Applicant urges that the immunoassay test strips of the instant invention comprise an improvement to obtain a test more quickly and accurately. This is not found persuasive because there is nothing to support applicant's asserted improvement. Applicant clearly admits that the test strips for performance of the immunoassay were commercially available (see pages 8-9).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant urges that the reference of Boger et al. does not teach lateral flow immunoassay test strips. This is not found persuasive for the reasons of record in view of the teachings of May et al. and Sun et al. and in view of the teachings in Boger et al. to use their holder for test devices for conducting immunochemical tests.

In this regard, applicant also urges that the reference of May et al. fails to specifically exemplify combinations of elements of the invention as are now claimed. This is not found persuasive because applicant's argument does not address the reasons and arguments of record regarding the obviousness and motivation for combinations of features. As set forth, May et al. specifically exemplify casings having apertures in the front or end of the casing for sample application, and specifically teach that the dry porous carrier communicates directly, or indirectly via a porous receiving member, with the exterior of the casing such that sample can be applied to the porous carrier (see e.g. page 3, or claims) and that combinations of features of the specifically exemplified embodiments were contemplated. As set forth, applicant's specification is silent on the presence or absence of an absorbent pad at the "absorbent or sample portions" of

the sample receiving portion of the test strip. Notwithstanding applicant's assertions to the contrary, either the porous carrier or the porous receiving member of May et al., which also may be present on the undisclosed structure of applicant's test strips, directly contacts the sample. For the reasons of record, one would have been motivated to provide a casing such as that depicted in Fig. 11 for a nitrocellulose test strip as depicted in Fig. 1 in view of the teachings in May et al. that such combinations were possible and that the sample receiving portion thereof was not sufficiently robust to protrude from a casing and one would have expected the combination to function as desired. Moreover, notwithstanding applicant's arguments to the contrary, there is nothing found in the disclosure of May et al. that excludes bathing an entire sample receiving portion of a dry porous carrier without a porous receiving member, as depicted in Fig. 1, when contacted with a sample in a casing such as that depicted in Figs. 5 or 6 or 11. The shape of the apertures and their placement on the end or front of the casing would seem obvious matters of design choice.

In response to Applicant's arguments that there are no specific suggestions to combine the references, the examiner recognizes that references cannot be arbitrarily combined and that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the common knowledge or common sense generally available to one of ordinary skill in the art. See: *In re Nomiya*, 184 USPQ 607 (CCPA 1975); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); or, *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). However, there is no requirement that the claimed invention or a motivation to make the modification be expressly articulated in any one or all of

the references. The test for combining references is what the combination of disclosures, taken as a whole, would suggest to one of ordinary skill in the art. See: *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); or, *In re McLaughlin*, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. See: *In re Bozek*, 163 USPQ 545 (CCPA 1969). A person of ordinary skill in the art, using common knowledge and common sense, is capable of fitting the teachings of multiple references together like pieces of a puzzle, regardless of the specific problem being addressed by the individual references. Any need or problem known at the time of the invention can provide a reason for combining elements of the different references. A person of ordinary skill in the art is also a person of ordinary creativity. In this case, for the reasons of record, ample motivations to combine the references with an extremely reasonable expectation of success have been set forth. As set forth, it would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have constructed the test strips in the device of May et al., as modified employing combinations of features of the specifically exemplified device embodiments therein as well as the ridges or other means which facilitate the preferred parallel alignment of the strips as taught in Boger et al., with reagents in a competitive immunoassay format for determination of drugs of abuse because May et al. teach the general applicability of their devices for determinations of analytes such as drugs with selection of appropriate binding reagents and Sun et al. teach that constructions wherein antigen in sample and antigen immobilized on the test strip compete for binding with mobile latex-labelled antibodies were well known alternatives in the art for determinations of drugs of abuse on immunoassay test strips, preferably with a plurality of

test strips for different drugs of abuse configured in a parallel arrangement for the determination of at least five drug of abuse analytes in a single device.

The terminal disclaimer filed on 21 May 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. patent No. 6,372,515 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JLG/
James L. Grun, Ph.D.
July 27, 2007

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